REMARKS

Claims 1, 2, and 4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of Measurement of Dielectric Properties of Subcutaneous Fat with Open-Ended Coaxial Sensors by Esko et al.("Measurement"). Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of "Measurement" and Sherwin (US 4,640,290). Claims 5-8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Campbell et al. (US 6,370,426) in view of "Measurement" and Penetration of Electromagnetic Fields of an Open-Ended Coaxial Probe between 1 MHz and 1 GHz in Dielectric Skin Measurements by Esko et al. ("Penetration"). Claims 11 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Malicki et al. (US 4,918,375) in view of "Measurement" or "Penetration" or Campbell et al. The examiner is requested to reconsider these rejections.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicants have amended claim 1 to recite, *inter alia*, a method for measuring tissue edema wherein "a distance between two electrodes of the probe being large enough in order for the electronic field to penetrate up to the subcutaneous fat tissue, and the said distance is about 6 mm to about 10 mm". Claim 1 further claims "an electromagnetic probe is placed on the skin during the measurement, and a capacitance of the

probe is proportional to a dielectric constant of the skin and subcutaneous fat tissue, which is further proportional to a water content of the skin". Support for this amendment may be found at, for example, page 4, lines 24-27.

Applicants submit that edema, as described in the application (for example see page 1, lines 3-14), is an abnormal accumulation of fluid beneath the skin or in one or more cavities of the body. Generally, the amount of interstitial fluid is determined by the balance of fluid homeostasis, and increased secretion of fluid into the interstitium or impaired removal of this fluid may cause edema (see Edema. (2010, February 18). In Wikipedia, The Free Encyclopedia. Retrieved 21:43, March 10, 2010, from http://en.wikipedia.org /w/index.php?title=Edema&oldid=344747493). Hence it can be said that tissue fluids that provide affects on edema are movable part of fluids. These fluids are called interstitial fluid.

Applicants submit that in the multilayered skin structure there are water molecules in the skin surface. The water molecules are coming to skin surface due to a diffusion process from air or from lower dermal part of the skin (called dermis). The resulting moisture is generally called skin surface hydration. Since there is no blood circulation or lymph vessels in the skin surface, edema in skin surface is impossible but possible in dermis due to a rich vascular network. Campbell merely discloses a method and an apparatus for measuring skin surface hydration mainly interested by the cosmetic industry. Skin edema described by the applicants is merely related to medicine and biological applications with

abnormal accumulation of movable tissue fluid into skin structures other than skin surface.

Campbell merely discloses a method and an apparatus for measuring relative hydration of a substrate. The force applied to and the temperature of the substrate during the measurements is used to ensure proper results of relative hydration. Campbell teaches that the invention can also be used to measure skin. Throughout the whole document of Campbell, a term of relative hydration is used. It is measured in sense of impedance and to be more specific capacitive reactance is measured.

However, Campbell **does not disclose anything about measuring edema**. The examiner states that Campbell discloses that a capacitance of the probe is measured to measure the skin water content or edema. Applicants respectfully disagree with the examiner. Applicants submit that if one skilled in the art were to measure substrate moisture or substrate hydration [as disclosed in Campbell at Col. 1, lines 16-17, and Col. 4, lines 49-65], **this would not mean that they can also measure edema**. This is because edema is a symptom that appears in deeper skin tissue **not on the skin surface** (skin surface can be determined as stratum corneum which forms the first tens of micrometers of skin). Applicants' present application discloses the deeper origin of edema, for example see page 3, lines 1-11. In particular, it is described that the "skin becomes thicker as the edema increases and the fat tissue moves further from the probe..." (see page 3, lines 8-9). This describes that edema is found in deeper skin tissue and hence it is impossible to detect by measuring just the superficial

part of the skin. Support for this can be found in the present application at page 3, lines 12-16 where it is said "...electric field is concentrated on the superficial layers of the skin and the measurement of edema is not possible." Therefore, applicants submit that skin surface hydration that is measured by the method and probe described by Campbell has nothing to do with edema detection. Hence, and as described also above, the edema cannot be found in the skin surface.

Instead, Campbell describes a method to measure relative hydration or relative moisture. These terms 'hydration' and 'moisture' are **irrelevant** when compared to the term 'edema', which is massive tissue fluid accumulation in tissue. Applicants' present application discloses that edema means accumulation of extra water in soft tissue and it leads increase in tissue volume (for example see Page 1, lines 3-14). In tissue edema affecting dermal skin and subcutaneous fat tissue water is thus movable while at (horny) skin surface there is no movable water and thus no edema. Applicants further submit that the terms moisture and hydration are generally only used when very superficial phenomena are described.

In conclusion, applicants submit that Campbell merely teaches measuring skin surface hydration, and **provides no teaching relating to tissue edema.**

Furthermore, the examiner admits that Campbell does "not disclose the capacitance of the probe as proportional to the dielectric constant of the skin and subcutaneous fat tissue and proportional to the water content of the skin, and is

silent to the frequency used, and the size of the probe". Another essential difference between the applicants' claimed invention and Campbell is that Campbell does not describe anything about the used frequency of electromagnetic field that, in addition to the probe dimensions, also effects on the measuring depth of the method. As claimed in applicants' claimed invention (and as disclosed throughout the present application, see for example, page 4, lines 5-9), the probe dimension has an essential influence on the measuring depth.

The article "Measurement" is a theoretical study to research how dielectric constant of subcutaneous fat can be calculated. In the article there is no impression or use of term edema. The method applies so called three layer model, consisting of skin's superficial part stratum corneum, epidermis/dermis and subcutaneous fat. Furthermore, the model requires using three different size probes to calculate dielectric constant of subcutaneous fat (see abstract of "Measurement"). Hence the purpose of the "Measurement" is to describe a method how to measure dielectric constant of the subcutaneous fat. In the study, the frequency of 300 MHz was applied to test the model after radiation-induced late skin injury which is called subcutaneous fibrosis (see Introduction, last sentence, page 476). Applicants emphasize that **there is no mention of measuring tissue edema at all in the article**. Furthermore, applicants submit that the purpose of applicants' claimed invention is not take subcutaneous fat into account which means determining of dielectrical values of the fat. Instead, applicants' claimed invention is directed to measure the whole volume seen by the probe and hence detect tissue edema. These

are different scopes between the article Measurement and applicants' claimed invention.

The article "Measurement" does not teach that there is direct known relationship between the dielectric constant of skin and its water content. This phenomena is thought to be known as such and it can also be found in the current application where it is stated that "These kinds of methods are used to measure the dielectric properties of tissue which are proportional to the water of tissue" (see page 2, lines 11-14).

Applicants submit that the article Measurement does not disclose that measuring frequency 300 MHz is used because subcutaneous fat is measured. Instead, in this article the frequency 300 MHz is used when so called three layer method and measurements with three different size probes are tested after radiation induced late skin reaction. The article suggests using three different size probes to measure dielectric properties of subcutaneous fat. Moreover, the use of three probes is a clear difference when comparing to applicants' claimed invention (where is no reference to using different size probes at the same time).

Applicants submit that the reason for using 300 MHz is addressed in the Discussion chapter where it is stated that at 300 MHz free and water bound to macromolecules has about the same value of dielectric constants (see "Measurement" Discussion page 483, second paragraph). Furthermore, **there is no mention in the article that these measurements are used to detect edema.**

The examiner also argues that Measurement "teaches ... a larger probe (10 mm)", however, the probe dimensions mentioned in the article "Measurement" require some clarification when compared to the dimensions referred in the current application. Briefly the dimension "2-10 mm" mentioned in the previously presented form of claim 1 is the same as (b-a) in the Figure 1 in page 476 of Measurement. The distance between electrodes (b-a) affects on the measuring depth of the probe. Hence the so called probe '10mm' in the article "Measurement" has a dimension (b-a) value of 3.5 mm. Respectively, the dimensions of the other probes used in the article were 1.8mm (for the probe '5mm') and 5.3 mm (for probe '15mm') see top of the page 479 and Figure 1 page 476 for clarification.

As mentioned above, claim 1 has been amended to recite "a distance between two electrodes of the probe ... the said distance is about 6 mm to about 10 mm". There is no teaching, disclosure, or suggestion in Measurement to provide a probe having electrodes spaced at a distance of about 6 mm to about 10 mm. Instead, Measurement teaches electrodes space at distances of 1.8 mm, 3.5 mm, and 5.3 mm.

Additionally, applicants submit that there is no suggestion to combine the references as the examiner is attempting to do (at least not until after reading applicants' patent application). In particular, a combination of Campbell and Measurement does not provide for tissue edema measurement. Campbell does not disclose anything about measuring frequency, relation of capacitance or dielectric constant and water content, probe size or deeper water measurement (as described above). The article Measurement is theoretical study where so called three

layer model and use of three different size probes are presented to calculate dielectric constant of subcutaneous fat (see abstract of "Measurement"). Hence the purpose of the "Measurement" is to describe a method how to measure dielectric constant of the subcutaneous fat itself and its combination with Campbell does not provide method to measure tissue edema. Neither Campbell nor the article "Measurement" mention anything about measuring edema.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. (see MPEP 2143.01, page 2100-98, column 1). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination (see MPEP 2143.01, page 2100-98, column 2). A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is **not sufficient** to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. (see MPEP 2143.01, page 2100-99, column 1) Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). >See also Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be

relied upon to provide the suggestion to combine references.)

In the present case, there is no teaching, suggestion, or motivation, found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to provide an electromagnetic probe that is placed on the skin during the measurement, and a capacitance of the probe is proportional to a dielectric constant of the skin and subcutaneous fat tissue, which is further proportional to a water content of the skin, and a distance between the two electrodes is about 6 mm to about 10 mm, as claimed in claim 1. The features of claim 1 are not disclosed or suggested in the art of record. Therefore, claim 1 is patentable and should be allowed.

Though dependent claims 2-6 contain their own allowable subject matter, these claims should at least be allowable due to their dependence from allowable claim 1. However, to expedite prosecution at this time, no further comment will be made.

Claim 7 has been amended to clarify applicants' claimed invention. Claim 7 claims "a high frequency unit for measuring the capacitance of the electromagnetic probe, wherein the high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a first range of approximately 20-50 MHz, wherein the high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a second range of approximately 50-500 MHz, wherein the first range corresponds to a measure of upper layers of the skin, and wherein the second range corresponds to a

measure of deep layers of the skin and the subcutaneous fat tissue ... a distance between two electrodes of the probe being large enough ... to penetrate up to and including the subcutaneous fat tissue". Support for this amendment may be found at, for example, page 4, lines 5-9.

Similar to the arguments presented above with respect to claim 1, Campbell fails to provide a teaching directed to measuring edema. Campbell does not disclose a device to measure tissue water content. Instead, Campbell teaches measuring skin surface hydration. Furthermore, there is no disclosure or suggestion of the capacitance of the probe as proportional to dielectric constant and water content of the skin. Additionally, the examiner admits that Campbell is silent as to the frequency used and the distance between the two electrodes of the probe.

The article "Measurement" does not teach that there is direct known relationship between the dielectric constant of skin and its water content. Additionally, the article Measurement does not disclose that a measuring frequency 300 MHz is used because subcutaneous fat is measured. Instead, in this article the frequency 300 MHz is used when so called three layer method and measurements with three different size probes are tested after radiation induced late skin reaction. The article suggests using three different size probes to measure dielectric properties of subcutaneous fat. Moreover, the use of three probes is clear difference when comparing to the current application where is no reference to use different size of the probes at the same time. Furthermore, there is no

mention in the article that these measurements are used to detect edema.

The article "Penetration" is directed to describing how the choice of measuring frequency affects on the measuring depth. The result is that at high frequencies (above 100 MHz) the open-ended coaxial probe measures the skin and subcutaneous tissue, and at lower frequencies (below 10 MHz) it measures mainly the superficial structures [see Conclusion, first paragraph, last sentence, p N174]. **There is no mention in the article that the method presented would be used to measure tissue edema.**

Neither Campbell, Measurement, nor Penetration teach or suggest a high frequency unit for measuring the capacitance of the electromagnetic probe, wherein the high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a first range of approximately 20-50 MHz, wherein the high frequency unit is arranged to measure the capacitance of the electromagnetic probe at a second range of approximately 50-500 MHz, wherein the first range corresponds to a measure of upper layers of the skin, and wherein the second range corresponds to a measure of deep layers of the skin and the subcutaneous fat tissue … a distance between two electrodes of the probe being large enough … to penetrate up to and including the subcutaneous fat tissue, as claimed in applicants' claimed invention.

Additionally, applicants submit that there is no suggestion to combine the references as the examiner is attempting to do (at least not until after reading applicants' patent application).

In the present case, there is no teaching, suggestion, or motivation, found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to provide for edema measurements, as **none of the documents mention of term edema or its measurement**. The features of claim 7 are not disclosed or suggested in the art of record. Therefore, claim 7 is patentable and should be allowed.

Though dependent claims 8 and 12 contain their own allowable subject matter, these claims should at least be allowable due to their dependence from allowable claim 7. However, to expedite prosecution at this time, no further comment will be made.

Claim 11 claims "placing an electromagnetic probe on the skin … transmitting a first portion of the first signal to the probe and through the skin and subcutaneous fat tissue … receiving a reflected signal from the skin and subcutaneous fat tissue through the probe … operating the phase detector in a saturated state, wherein signal amplitudes from the reflected signal and the second portion of the first signal form the saturated state … and calculating a water content of the skin based on the dielectric constant".

Malicki et al. discloses a reflectrometric moisture meter for capillary-porous materials, especially for the soil. The measuring is made by using oblong dagger-like electrodes inserted into the soil (see col. 2, lines 11-12). As mentioned in the title of the patent, this meter is for the measuring of soil. There is no mention or description of

measuring of the edema or measuring the skin. Applicants further submit that **skin is not a capillary-porous material as described in patent of Malicki**. In particular, Malicki teaches that the meter "can be applied for any such capillary-porous material which allows introduction of the probe in a non-destructive way … [s]uch materials include: the soil, agricultural products (grain, hop cones, tobacco leaves, hay), food industry products (flour, bakery products), wood, moulding sand, subgrades, building foundations etc.".

Similar to the arguments presented above with respect to claims 1 and 7, Campbell fails to provide a teaching directed to measuring edema. Campbell does not disclose a device to measure tissue water content. Instead, Campbell teaches measuring skin surface hydration. Furthermore, there is no disclosure or suggestion of the capacitance of the probe as proportional to dielectric constant and water content of the skin. Additionally, the examiner admits that Campbell is silent as to the frequency used and the distance between the two electrodes of the probe.

The article "Measurement" does not teach that there is direct known relationship between the dielectric constant of skin and its water content. Additionally, the article Measurement does not disclose that a measuring frequency 300 MHz is used because subcutaneous fat is measured. Instead, in this article the frequency 300 MHz is used when so called three layer method and measurements with three different size probes are tested after radiation induced late skin reaction. The article suggests using three different size probes to measure dielectric properties of subcutaneous fat. Moreover, the use

of three probes is clear difference when comparing to the current application where is no reference to use different size of the probes at the same time. Furthermore, there is no mention in the article that these measurements are used to detect edema.

The article "Penetration" is directed to describing how the choice of measuring frequency affects on the measuring depth. The result is that at high frequencies (above 100 MHz) the open-ended coaxial probe measures the skin and subcutaneous tissue, and at lower frequencies (below 10 MHz) it measures mainly the superficial structures [see Conclusion, first paragraph, last sentence, p N174]. There is no mention in the article that the method presented would be used to measure tissue edema.

Neither Malicki, Campbell, Measurement, nor Penetration teach or suggest anything relating to measuring tissue edema.

Applicants submit that there is no disclosure or suggestion in the art of record of operating the phase detector in a saturated state. **Applicants again note that the examiner has not pointed out any prior art reading on this feature of the invention.**

Applicants further submit that there is no suggestion to combine the references as the examiner is attempting to do (at least not until after reading applicants' patent application). For example, Malicki teaches that the oblong dagger-like electrodes 1a, 1b, 1c, have lengths of 0.1 m, 0.25 m, and 0.5 m (see col. 6, lines 64-68). These large electrodes are **inserted into the soil** and each spaced several meters from

each other (see Fig. 1). There is no disclosure or suggestion in Malicki of inserting the oblong dagger-like electrodes into the skin of a person. Thus, it is clear that the teachings of Malicki are directed to industrial applications. Whereas, the teachings of Campbell, Measurement, and Penetration are directed to measurements on human skin.

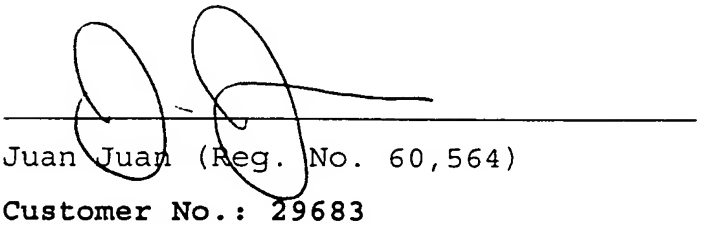
In the present case, there is no teaching, suggestion, or motivation, found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art, to provide the method as claimed in claim 11. The features of claim 11 are not disclosed or suggested in the art of record. Therefore, claim 11 is patentable and should be allowed.

Applicants also note that the article "Variational Formulation of ..." (cited by the examiner) is a theoretical study where a mathematical model to take subcutaneous fat into account is presented when open-ended probe measurements on the skin are performed. Now term takes into account means that dielectric value of the skin can be measured without effect of subcutaneous fat on the measurement. Again there is no mention in the article that the method presented would be used to measure tissue edema.

For all of the foregoing reasons, it is respectfully submitted that all of the claims now present in the application are clearly novel and patentable over the prior art of record. Accordingly, favorable reconsideration and allowance is respectfully requested. If there are any additional charges with respect to this Amendment or otherwise, please charge

deposit account 50-1924 for any fee deficiency. Should any unresolved issue remain, the examiner is invited to call applicants' attorney at the telephone number indicated below.

Respectfully submitted,



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3/18	amendment	873.0134.U1(US)	WM	JP	✓		✓	✓	
3/18	Formal Drawings	873.0183.U1(US)	WM	Em	✓		✓	✓	
3/18	response	879.0122.U1(US)	WM	JP	✓		✓	✓	